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In the

Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Petitioner,

v.

CONCANNON, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF PETITIONER

DEBORAH J. LA FETRA
Counsel of Record
Pacific Legal Foundation
10360 Old Placerville Road,
Suite 100
Sacramento, California 95827
Telephone: (916) 362-2833
Facsimile: (916) 362-2932

Counsel for Amicus Curiae
Pacific Legal Foundation

37 pp

QUESTION PRESENTED

Whether a Maine statute providing for affordable prescription drugs, which penalizes companies that won't drop prices for uninsured residents, violates the Constitution's Commerce Clause.

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INTEREST OF AMICUS CURIAE

Pacific Legal Foundation (PLF) was founded 29 years ago and is widely recognized as the largest and most experienced nonprofit legal foundation of its kind. PLF litigates matters affecting the public interest at all levels of state and federal courts and represents the views of thousands of supporters nationwide. PLF is an advocate for limited government, individual rights, and free enterprise and believes public officials must be respectful of the constitutional limitations on federal power. PLF established a Free Enterprise Project in which we submit amicus briefs in cases impacting America's economic vitality. For example, PLF filed amicus briefs in *Chevron, U.S.A., Inc. v. Echazabal*, 122 S. Ct. 2045 (2002), and *Adams v. Florida Power Corp.*, 122 S. Ct. 643 (2001). PLF believes that Maine's statutory threat to impose pharmaceutical price controls overstepped the bounds of its sovereignty and intrudes unconstitutionally on the American national marketplace.[1]

STATEMENT OF THE CASE

In May, 2000, Maine enacted an Act to Establish Fairer Pricing for Prescription Drugs, thus creating the Maine Rx Program. The program, funded wholly by "rebates" from drug manufacturers, subsidizes retail prescription drug purchases for Maine citizens. Me. Rev. Stat. tit. 22, § 2681(3)-(5) (2001). The law provides that manufacturers will make payments to the State based on the quantity of drugs dispensed to Maine Rx participants by retailers. Me. Rev. Stat. tit. 22, § 2681(4).

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[1] Pursuant to this Court's Rule 37.3(a), all parties have consented to the filing of this brief. Letters evidencing such consent have been filed with the Clerk of the Court.

Pursuant to Rule 37.6, Amicus Curiae affirms that no counsel for any party authored this brief in whole or in part and that no person or entity made a monetary contribution specifically for the preparation or submission of this brief.

Using the Maine Rx program, residents can purchase drugs from retail pharmacies at discounts funded by the rebates. Me. Rev. Stat. tit. 22, § 2681(5). The "rebate agreements" are not freely entered into—the Act mandates that manufacturers "shall" subsidize Maine Rx drugs. Me. Rev. Stat. tit. 22, § 2681(3). The Act enforces Maine Rx provisions using Medicaid regulatory powers to require "prior authorization" by state officials for prescriptions dispensed to Medicaid patients. Me. Rev. Stat. tit. 22, § 2681(7). Prior authorization creates a procedural obstacle to Medicaid patients' access to listed drugs, which in turn reduces Medicaid-funded purchases of those drugs.

In addition, the Act provides that failure to comply is considered a violation of the Maine Unfair Trade Practices Act, which allows a private right of action and additional penalties. Me. Rev. Stat. tit. 10, §§ 212-13. Finally, and most ominously, the Act contemplates imposing direct price controls on retailers in 2003 if the Maine Rx program does not lower drug prices to the State's satisfaction. Me. Rev. Stat. tit. 22, § 2693(1)(B).

The Pharmaceutical Research and Manufacturers of America sued to invalidate Maine Rx on the grounds that the Act violates the dormant Commerce Clause and was preempted by the Medicaid statute under the Supremacy Clause. The district court agreed but the First Circuit Court of Appeals reversed, finding that Maine Rx only regulates in-state activities and sets forth prior authorization procedures consistent with those permitted by Medicaid law. The First Circuit held that the Act does not regulate out-of-state prices, either on its face or by its effect. *Pharmaceutical Research and Manufacturers of America v. Concannon (PhRMA)*, 249 F.3d 66, 81 (2001). Furthermore, the court held that there is nothing in the Act tying the in-state prices of prescription drugs to out-of-state prices, or imposing controls on wholly out-of state transactions. *Id.* at 81-82. On a facial challenge of the statute, the court below refused to hold that the "negotiators' " potential for abuse actually

regulates drug prices. *Id.* at 82. The court thus concluded that while Maine Rx regulates a large amount of in-state commerce, there is no actual extraterritorial reach, and the Act is not per se invalid. *Id.*

The First Circuit also reviewed the act under the balancing test from *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970): "Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." Balancing the increased access to prescription drugs for residents of Maine against the drug manufacturers' possible loss of profits, the court held that the "putative local benefits" clearly outweigh the incidental "effects on interstate commerce." *PhRMA*, 249 F.3d at 83-84. Thus, the First Circuit found no dormant Commerce Clause violation under either the strict per se test or the lesser *Pike* balancing test.

On June 28, 2002, this Court granted certiorari.

SUMMARY OF ARGUMENT

The Constitution "was framed upon the theory that the peoples of the several states must sink or swim together, and that in the long run prosperity and salvation are in union and not division." *Baldwin v. G. A. F. Seelig, Inc.*, 294 U.S. 511, 523 (1935). That is, individual residents of the several States are citizens of a nation, and some state statutes are incompatible with this ideal. Stone, Geoffrey R., et al., *Constitutional Law* 293-94 (3d ed. 1996). Furthering this ideal, the Commerce Clause of the Constitution created an "area of free trade among the several States." *Associated Indus. of Missouri v. Lohman*, 511 U.S. 641, 650 (1994) (quoting *McLeod v. J. E. Dilworth Co.*, 322 U.S. 327, 330 (1944)). Despite these benefits of free trade, states have incentives to enact regulations or taxes that impose costs on other states while the benefits remain in the

state. Posner, Richard A., *Economic Analysis of Law* § 25.3, at 699 (5th ed. 1998). This is precisely what Maine seeks to accomplish—lower drug prices for its own residents at the expense of residents outside the state's borders.

Case law interpreting the dormant Commerce Clause has never approached a problem precisely like that posed by Maine Rx. In this case, the state imposed a facially-neutral statutory scheme that has the effect of regulating out-of-state transactions to obtain an economic advantage for its own residents. While pharmaceutical consumers living in Maine enjoy lower drug prices, the pharmaceutical companies' natural reaction to increase drug prices for other consumers outside the state presents a potentially significant impact on interstate commerce. Maine's manipulation of interstate commerce for the economic advantage of its residents undercuts the national free-market policies underlying the dormant Commerce Clause and is akin to the protectionism traditionally held unconstitutional under that provision.

America's history is based on our willingness to take risks, and on free-market support of innovation. In considering the constitutionality of Maine Rx, the Court should act to protect the American common market in pharmaceuticals—the world leader in this critical industry. The American common market in pharmaceuticals is a worldwide success, benefitting hundreds of millions of people. Drug manufacturers reinvest much of their profits to fund the high risk research essential to developing innovative new drugs and therapies. Controlling drug prices limits pharmaceutical research and development (R&D), thus delaying or diminishing the life-enhancing possibilities that such research will yield. The Maine Rx requirements that pharmaceutical companies provide Medicaid-level discounts to all Maine residents or face price controls serve only to benefit Maine drug consumers while this manipulation of interstate commerce will force consumers in other states to face increased drug prices to compensate for

revenue lost in Maine. If Maine carries through on its threat to impose price controls, American patients in general will pay the price in reduced health. For the reasons set forth below, the decision of the First Circuit Court of Appeal should be reversed.

ARGUMENT

I

MAINE RX IS PROTECTIONIST LEGISLATION ENACTED IN VIOLATION OF THE DORMANT COMMERCE CLAUSE

The Commerce Clause provides that "the Congress shall have Power . . . [t]o regulate commerce . . . among the several States . . . ." U.S. Const. art. I, § 8, cl. 3. When the Framers designed the United States Constitution, they included this clause to prevent economic barriers to trade from threatening the new political order. *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 807 (1976) (Commerce Clause designed to help the states form "a cohesive whole" after the revolution). This Court has long held that the flip side of the Commerce Clause—the "dormant" Commerce Clause—forbids State regulation of interstate commerce. *H. P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 537-38 (1949). As Justice Jackson wrote for the Court:

> Our system, fostered by the Commerce Clause, is that every farmer and every craftsman shall be encouraged to produce by the certainty that he will have free access to every market in the Nation, that no home embargoes will withhold his exports, and no foreign state will by customs duties or regulations exclude them.

Id. at 539. The Framers sought to curb interstate exploitation by stronger states and by those with geographic advantages. The Federalist No. 6 (A. Hamilton) (Rossiter ed. 1961);

1 Records of the Federal Convention of 1787 at 19, 164 (M. Farrand ed. 1911).

The fundamental prohibition of the dormant Commerce Clause, as interpreted by the Supreme Court, is against "discrimination"—i.e., "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter." *Oregon Waste Sys., Inc. v. Department of Envtl. Quality*, 511 U.S. 93, 99 (1994). A state statute that discriminates on its face against out-of-state businesses or goods is "virtually per se unlawful" and must be justified under the "strictest scrutiny," a standard that the state almost never can satisfy. *Id.* at 101; *City of Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978). A state regulation that is not facially discriminatory may nonetheless be unlawful if the burdens it imposes on interstate commerce exceed the benefits. *Pike*, 397 U.S. at 142. The Court only rarely strikes down statutes under this balancing test. Petragnani, Amy M., Comment, *The Dormant Commerce Clause: On Its Last Leg*, 57 Alb. L. Rev. 1215, 1249 (1994) ("The Court is no longer applying the dormant Commerce Clause to overturn state legislation unless the statute is clearly or facially discriminatory.").

This Court's dormant Commerce Clause cases are supposed to follow one of two theories. The first theory is that the dormant Commerce Clause "provide[s] an economic blueprint for the nation's economic functioning," while the second theory purports that the clause "fulfill[s] a political vision of a federal government responsive to the needs of all citizens while at the same time respecting and honoring the institutional interests of the States." Lawrence, Michael A., *Toward a More Coherent Dormant Commerce Clause: A Proposed Unitary Framework*, 21 Harv. J.L. & Pub. Pol'y 395, 411 (1998). In this case, PhRMA argued the economic blueprint theory by analogizing Maine's statute to price affirmation statutes that have been declared unconstitutional by this Court, under a "practical effect" test. Maine, on the other

hand, argued the political vision theory, asserting that the benefits to the state must be weighed against the burden to commerce. Phelps, Whitney Magee, *Maine's Prescription Drug Plan: A Look into the Controversy*, 65 Alb. L. Rev. 243, 255 (2001). Thus, the "economic blueprint" theory maps to the strict per se invalidity test (applied to both extraterritorial reach and to discriminatory legislation) while the "political vision" theory maps to the *Pike* balancing test. These separate lines of inquiry have led to a morass of confusion—even to members of this Court, who describe the analysis as "hopelessly confused," *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 706 (1981) (Rehnquist, J., dissenting), a "quagmire," *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 210 (1994) (Scalia, J., concurring), and "not always . . . easy to follow." *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 87 (1987).

The basic problem is that the two supposedly separate analyses have been blurred, using the language from one test to support a result that purportedly was arrived at using the other test. For example, the Court has struck down facially neutral state statutes that it determines to be discriminatory in effect. In *West Lynn Creamery*, 512 U.S. at 190-91, the Court struck down a Massachusetts milk pricing order that imposed a tax on all milk and used the proceeds to fund a subsidy to in-state milk producers. Although the milk tax was facially non-discriminatory because it applied equally to all milk, the Court invalidated the pricing order based on a "case-by-case analysis of purposes and effects" rather than legal doctrine. *Id.* at 201. In *American Trucking Associations v. Scheiner*, 483 U.S. 266, 286 (1987), the Court struck down facially neutral taxes on trucks based on their "practical effect" of imposing "a cost per mile on appellants' trucks that is approximately five times as heavy as the cost per mile borne by local trucks." *See also Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 350-54 (1977). In each case the state statute was neutral on its face, which ordinarily would have resulted in the Court's

applying a balancing test that rarely leads to invalidation of the statute. Instead, the Court looked to the practical effect of the statute and found that it unconstitutionally interfered with free trade. Drahozal, Christopher R., *Preserving the American Common Market: State and Local Governments in the United States Supreme Court*, 7 S. Ct. Econ. Rev. 233, 245 (1999) (*Preserving the American Common Market*).

On top of this confusion comes this case—unlike any other in the dormant Commerce Clause canon. Maine wants lower drug prices for consumers within its border, but does not want Maine taxpayers to pay for the discount via the state treasury. Instead, the state enacts a statutory scheme to shift to the pharmaceutical companies the cost of the marginal difference between the market value of the drugs and the price the state believes is fair. Because those companies are based outside of Maine and engaged in interstate commerce, the state must bear the burden of showing that its regulation does not have the potential to cause significant effects on interstate commerce. One factor the Court should consider is the impact on interstate commerce if Maine's regulation is replicated in other states, regardless of whether that replication is "the sincerest form of flattery" or in retaliation.

A. A Statute Violates the Dormant Commerce Clause If It Is Protectionist, Regardless of Whether It Is Discriminatory

The dormant Commerce Clause preserves "a national market for competition undisturbed by preferential advantages conferred by a State upon its residents or resident competitors." *General Motors Corp. v. Tracy*, 519 U.S. 278, 299 (1997). When states burden commerce outside their borders, they interfere in policy choices of other states or of the federal government or both. If this interference devolves into economic warfare, the ultimate losers will be the smaller and weaker states and those with less favorable geography—like Maine. Collins, Richard B., *Economic Union As a*

Constitutional Value, 63 N.Y.U. L. Rev. 43, 64 (1988) (*Economic Union*). The free-trade objectives incorporated in the dormant Commerce Clause further the efficient allocation of resources within American society, just as free trade among nations helps to further the efficient allocation of resources in the world. Gifford, Daniel J., *Federalism, Efficiency, the Commerce Clause, and the Sherman Act: Why We Should Follow a Consistent Free-Market Policy*, 44 Emory L.J. 1227, 1227-28 (1995).

Indeed, this Court frequently asserts that the dormant Commerce Clause calls for an American "common market." *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 423 (1994); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 293 (1980); *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. at 350; *H. P. Hood,* 336 U.S. at 538. Tying this economic policy to political processes, regulations must allow those primarily affected by the regulation to register their approval or disapproval about the measure through the political process directly by voting. *Southern Pac. Co. v. Arizona ex rel. Sullivan*, 325 U.S. 761, 767 n.2 (1945) ("[T]o the extent that the burden of state regulation falls on interests outside the state, it is unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected."). Regulations are like other products: when costs are not borne by producers, these costs are disregarded, and producers create more of the products than an efficient market would supply. When costs imposed by legislation are exported outside the state, there is less political pressure to minimize these costs and there is a greater chance that the law will reduce aggregate welfare. *Economic Union*, 63 N.Y.U. L. Rev. at 68.

A common understanding of protectionism is the act of guarding or shielding one's own. *Economic Union*, 63 N.Y.U. L. Rev. at 74 ("Classic protectionism meant shielding domestic producers against competition from imports."). However, the dormant Commerce Clause doctrine

applies to both producer *and consumer* favoritism. *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, 580 (1986) ("Economic protectionism is not limited to attempts to convey advantages on local merchants; it may include attempts to give local consumers an advantage over consumers in other States."). In *Camps Newfound/Owatonna v. Town of Harrison*, 520 U.S. 564, 575-76 (1997), the Court rejected the Town's argument that the dormant Commerce Clause concerns the protection of out-of-state producers only, holding instead that impermissible protection can come both in the form of preferences to local merchants and advantages to local consumers: "[I]t matters little that it is the camp that is taxed rather than the campers. . . . The economic incidence of the tax falls at least in part on the campers . . . ." *Id.* at 580; *see also Philadelphia v. New Jersey*, 437 U.S. at 627 ("[A] State may not accord its own inhabitants a preferred right of access over consumers in other States to natural resources located within its borders.").

Protectionist practices are repugnant simply because they are directly inconsistent with the quest for national unity. O'Grady, Catherine Gage, *Targeting State Protectionism Instead of Interstate Discrimination Under the Dormant Commerce Clause*, 34 San Diego L. Rev. 571, 626-27 (1997) (*Targeting State Protectionism*). Protectionism ought to be targeted as the evil prohibited by the dormant Commerce Clause because it is "hostile in its essence" and likely to cause resentment and invite retaliation. Regan, Donald H., *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 Mich. L. Rev. 1091, 1113-14 (1986). States do not have the right to regulate transactions occurring outside their borders regardless of whether they intend to discriminate against interstate commerce. A state may not purposefully manipulate the channels of interstate commerce to isolate the state from the national economy or

protect resident economic interests from the national market.[2] A protectionist statute purposefully makes use of the state's own borders or the network of the interstate market to improve the position of local residents simply because they are local. *See Targeting State Protectionism*, 34 San Diego L. Rev. at 588.

The Court has applied this anti-protectionist theory in several cases, most frequently those that apply the "per se invalidity" higher level of scrutiny. In *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, the Court invalidated a New York law that set price ceilings for liquor sold in-state based on the seller's lowest price in other states. This Court held that a state law that "directly regulates or discriminates against interstate commerce" will generally be struck down "without further inquiry." *Id.* at 579. The Court presumed that the law improperly burdened interstate commerce by forcing up the price of liquor in other states, particularly smaller ones. *Id.* at 582-84. In other words, New York was exploiting market power as a large consumer to gain advantage at the expense of smaller states. The Court was willing to assume the law had these effects, even in the absence of proof. *Id.*[3]

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[2] This Court need not decide whether the protectionism or discrimination was deliberate. *See Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. at 352 ("[W]e need not ascribe an economic protection motive to the North Carolina Legislature to resolve this case . . . ."); *Pike*, 397 U.S. at 145-46 (finding intent irrelevant); *Halliburton Oil Well Cementing Co. v. Reily*, 373 U.S. 64, 72 (1963) (acknowledging that state tax law at issue may have discriminated accidentally but striking law down anyway). Most of the dormant Commerce Clause opinions say nothing about intent.

[3] The Court was unwilling to "indulg[e] the . . . assumption" that the state would be sensitive to Commerce Clause concerns in the implementation of its statute. "The protections afforded by the

(continued...)

Similarly, in *Healy v. Beer Institute*, 491 U.S. 324, 336 (1989), the Court held:

> [The] Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, . . . [and] a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority, and is invalid . . . .

The critical inquiry in determining a state law's validity is whether it has the "practical effect" of regulating commerce occurring outside the state's borders. In *Healy* and *Brown-Forman*, this Court held that a State may not regulate in a manner that sets prices on transactions between buyers and sellers in other States, to ensure a more favorable price structure for domestic consumers at the expense of consumers in other States. Under these cases, the laws were subject to a "virtually per se rule of invalidity" under the dormant Commerce Clause. It did not matter if the statute did not on its face regulate out-of-state transactions.

In our federal system, uniform national standards, where appropriate, are for Congress to set. As the Founders knew and this Court's dormant Commerce Clause jurisprudence has recognized, allowing one state to impose its laws on commerce nationwide would place commerce at the mercy of local, parochial interests and create an anarchy of conflicting state legal regimes which would destroy commercial confidence and create hostility between the states. *See, e.g., C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. at 406 (O'Connor, J.,

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[3] (...continued)
Commerce Clause cannot be made to depend on the good grace of a state agency." *Id.* at 582 n.5.

concurring) (differing state regimes regulating flow of solid waste would result in "the type of balkanization the Clause is primarily intended to prevent"). State laws regulating corporate takeovers, for example, restrain share sales occurring entirely outside the regulating state. They prevent some takeovers altogether and raise costs of others substantially. This Court struck down one such law in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982). In that case, the challenged Illinois statute regulated corporations of other states, corporations doing little or no business in the state, and corporations lacking local shareholders. *Id.* at 645-46. The critical factor was that the regulated transactions between buyers and sellers outside Illinois were not sufficiently Illinois's affair to justify so much interference. *Id.* at 646. (This was the largest point of differentiation with *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. at 93, upholding an Indiana takeover statute that was confined to corporations that were chartered in the state, had a large number of local shareholders, and were principally based or had major operations there.)

In sum, an approach to dormant Commerce Clause challenges based on protectionism furthers several compelling policies: The approach prevents states from engaging in overtly hostile acts against their sister states, thus provoking retaliation by competitor states. *Oklahoma Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179-80 (1995). Striking down protectionist legislation protects weaker states from acts by bigger, stronger states offering benefits to their own citizens at the expense of Americans outside their state borders. Moreover, a rule based on anti-protectionism serves the virtues of simplicity and certainty. *See Economic Un[illegible]*, 63 N.Y.U. L. Rev. at 113.

B. Maine Rx Is Protectionist Because Its Manipulation of Drug Prices for the Economic Advantage of Maine's Drug Consumers Causes Significant Impacts on Interstate Commerce

The protectionist nature of Maine Rx is demonstrated by its impact on Maine residents versus non-Maine residents. The Court should ask: "What is the potential impact on the rest of the American common market?" A manufacturer may offer special pricing in a limited number of states. But there is a real question as to how much a manufacturer could absorb if it is expected to sharply cut prices for residents of many states. Palumbo, Francis B., *The Role of the State As a Drug Purchaser*, 56 Food Drug L. J. 267, 271-72 (2001) (*Role of the State*). So while the facts of this case involve the relatively small Maine market, the Court should consider what would happen if California were to adopt a "California Rx" program.[4] Or if California joined with some other populous states to form a "Big Multi-State Rx" program. This is not outside the realm of possibility. For example, Maine Rx is not Maine's first attempt to obtain lower drug prices for its residents. In 2000, a coalition of Maine, Vermont, and New Hampshire solicited bids from pharmacy benefit manager organizations to run all three states' drug programs. The three states, which collectively have programs with over one million enrollees and one billion dollars in annual drug expenditures, sought to capitalize on their combined market share power by negotiating discounts without limitations. In any of these scenarios, the price cuts for residents within states with these programs would likely increase prices charged to customers in other states. *See, e.g.* General Accounting Office (GAO), Report to Congressional Requesters, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*,

[4] In 2000, Maine had 1.27 million residents and California had 33.87 million residents. U.S. Census (2000) (http://quickfacts.census.gov) (visited Sept. 10, 2002).

GAO/HEHS-00-118 (2000) (a study of whether Federal Supply Schedule (FSS) prices should be extended to other programs concluded that prices paid by others would have to rise). The larger the group that would be newly entitled to receive a governmentally mandated price, the greater the incentive for drug manufacturers to raise that price for other purchasers. *Id.* So the states, in providing "coverage" for noninsured residents, may indeed be passing on the bill to other citizens in the form of increased premiums or decreased access in their private or employer-based health programs, as these programs may reduce coverage if the state steps in. *Role of the State*, 56 Food Drug L. J. at 272.

Two aspects of Maine Rx demonstrate the statute's protectionist nature. First is the provision forbidding companies from altering their distribution channels. Me. Rev. Stat. tit. 22. § 2697(2)(D). No drug manufacturers are located in Maine, and only one distributor resides there. As the district court correctly noted, the Act's purpose and effect is to lower the revenues received by these out-of-state manufacturers on drugs to be sold in Maine. *See Pharmaceutical Research and Manufacturers of America v. Commissioner*, 2000 U.S. Dist. LEXIS 17363, at *15 (D. Me. Oct. 26, 2000) (observing that the practical effect of the Act is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that are destined for Maine). No valid argument can be made that the Act, in its intent or practical effect, does not reach transactions between manufacturers and distributors. Pancoast, Abigail B., Comment, *A Test Case for Re-evaluation of the Dormant Commerce Clause: The Maine Rx Program*, 4 U. Pa. J. Const. L. 184, 199 (2001) (*Test Case*).

Maine correctly foresaw that leaving the state would otherwise be the reasoned response of the companies. In a boycotting effort, three prescription companies decided not to ship their medicines directly to Maine, using out-of-state wholesalers to supply non-Medicare recipients in the state.

Barrington, Conrad J., Note and Comment, *Pharmaceutical Research and Manufacturers of America v. Concannon and Maine's Prescription Drug Rebate Statute: A Twenty-First Century Solution to the Medicaid Crisis*, 23 Whittier L. Rev. 1127, 1132 (2002) (AstraZeneca, Bristol-Myers Squibb, and Smith-Kline Beecham). These companies' quick departure from the market vividly demonstrates the adverse incentives created by Maine Rx. This Court has held that "strong incentives," in lieu of direct regulation, are sufficient to implicate the dormant Commerce Clause. *Camps Newfound/Owatonna*, 520 U.S. at 578.

Second, when Maine requires pharmaceutical companies to offer discounted drug prices to Maine residents, the companies can be expected to recoup their losses by increasing prices paid by other people beyond Maine's borders. The GAO addressed this very issue in a 2000 study of whether FSS prices should be extended to other programs. The GAO concluded that prices paid by others would have to rise. GAO, Report to Congressional Requesters, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*, GAO/HEHS-00-118. So Maine, by providing "coverage" for noninsured residents, may be passing on the bill to other citizens in the form of increased premiums or decreased access in their private or employer-based health programs. *See Role of the State*, 56 Food Drug L.J. at 271. Maine Rx sets the goal of "negotiations" between the manufacturers and the state to be FSS prices, which are the best prices obtained by any private purchaser. A private health plan cannot possibly negotiate a better price from a drug manufacturer. Then, Maine Rx Program participants are not subject to formularies, unlike the beneficiaries of many health plans that negotiate discounts from drug

manufacturers.[5] Uninsured and insured residents alike may all enroll in the Maine Rx Program and rely on private purchasers in other states to negotiate best-price discounts. In this scenario, purchasers in other states will have to pay more because drug manufacturers will be less inclined to give competitive discounts when they have to give the same discounts to the entire state of Maine. Stambaugh, Christopher R., Note, *State Price Control Laws Are the Wrong Prescription for the Problem of Unaffordable Drugs*, 12 Fordham Intell. Prop. Media & Ent. L.J. 897, 924 (2002) (*Wrong Prescription*).

The State can be expected to respond to this argument by asserting that the manufacturers *voluntarily* choose to provide rebates to Maine Rx participants. But Maine did not intend these agreements to be voluntary—in deciding to subject uncooperative manufacturers to the prior authorization requirement, the state had obviously determined that a voluntary program would not be sufficiently effective. The court below accepted the state's argument in this regard, holding that Maine Rx "merely says that the Commissioner of the Maine Department of Human Services shall use 'best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program . . . .'" *PhRMA*, 249 F.3d at 82 (citing Me. Rev. Stat. tit. 22, § 2681(4)(B)).

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[5] Although Maine Rx describes the State's role as a Pharmacy Benefit Manager (PBM), Me. Rev. Stat. tit. 22, § 2681(1), real PBMs use formularies to help control drug costs by (1) encouraging the use of formulary drugs through compliance programs that inform physicians and enrollees about which drugs are on the formularies; (2) limiting the number of drugs a plan will cover; or (3) developing financial incentives to encourage the use of formulary products. GAO Letter Report to the Honorable Ron Wyden, House of Representatives, *Pharmacy Benefit Managers: Early Results on Ventures with Drug Manufacturers*, GAO/HEHS-96-45 (1995). Maine Rx does not use formularies.

Thus the First Circuit held that the program was voluntary and the manufacturers could withdraw at any time. *Id.*

This holding represents willful blindness. The statute says manufacturers "shall" provide rebates (Me. Rev. Stat. tit. 22, § 2681(3)) and the very nature of the program demands manufacturers' compliance. First, the program contained the unconstitutional "anti-profiteering" sections, threatening treble compensatory damages, punitive damages, and civil penalties up to $100,000 if a company demanded terms the state determined to be "unreasonable" or if a manufacturer alters its business practices to avoid Maine's new law. Me. Rev. Stat. tit. 22, § 2697.[6] Second, Maine Rx imposes the prior authorization requirement on nonparticipants. Me. Rev. Stat. tit. 22, § 2681(7). Prior authorization means that a state bureaucrat has to approve a medication a doctor chooses for his or her patients. It slows down the dispensing procedure so much that instead of waiting for approval, doctors and patients are likely to seek alternative therapies. *Wrong Prescription*, 12 Fordham Intell. Prop. Med. & Ent. L. J. at 921. As a consequence, market shares of drugs that require prior authorization decline significantly. *Pharmaceutical Research and Manufacturers of America v. Medows*, 184 F. Supp. 2d 1186, 1192 (N.D. Fla. 2001) (naming drugs taken off a preferred drug list and requiring prior authorization: market share of Imitrex fell from 60% to 6%; the market share of Prilosec fell from 38% to 4%, and the market share of Allegra fell from 17% to 1%). The two provisions combined can only be construed as a requirement. *Test Case*, 4 U. Pa. J. Const. L. at 196.

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[6] The district court declared these provisions unconstitutional and the state did not appeal that ruling. They remain relevant to the inquiry before this Court, however, as they demonstrate that Maine never anticipated that manufacturers would voluntarily comply with the "negotiated" rebates.

This Court has expressly held that a state law using the state's leverage in one market where it does participate to achieve a separate regulatory purpose is subject to the dormant Commerce Clause as a state regulation and is not market participation. *South-Central Timber Development, Inc. v. Wunnicke*, 467 U.S. 82, 96-98 (1984) (holding that Alaska's statute limiting buyers of its timber to those who agreed to process the purchased timber in Alaska to be subject to the dormant Commerce Clause). *Test Case*, 4 U. Pa. J. Const. L. at 198. The court below recognized that Maine is not acting as a typical market participant as it neither buys nor sells pharmaceuticals (*PhRMA*, 249 F.3d at 80), but it erred by its failure to acknowledge the regulatory sanctions imposed by the program. Thus, Maine Rx fails dormant Commerce Clause analysis because it regulates extraterritorial economic transactions by imposing either a rebate agreement or a prior authorization requirement on drugs that are part of an out-of-state sale between out-of-state manufacturers who do not grant rebates, and out-of-state wholesalers and distributors. *See Test Case*, 4 U. Pa. J. Const. L. at 198.

As shown above, Maine Rx is likely to harm non-Maine drug consumers because pharmaceutical companies will seek to recoup the discounts they are required to offer to Maine residents by selling drugs outside the state at higher prices. As additional, and more populous, states replicate Maine's statutory scheme, the impact on consumers in those states without an "Rx" statute becomes more severe, causing a significant impact on interstate commerce as a whole. This protectionist policy should be held to be a violation of the dormant Commerce Clause.

II

MAINE RX DAMAGES THE AMERICAN COMMON MARKET

For private enterprise to flourish, a federal system must "prevent[] the lower governments from using their regulatory authority to erect trade barriers against the goods and services from other political units." Weingast, Barry R., *The Economic Role of Political Institutions: Market-Preserving Federalism and Economic Development*, 11 J.L. Econ. & Org. 1, 4 (1995) (*Market-Preserving Federalism*). The creation and preservation of a national common market is a central feature of "market-preserving federalism"—federalism that fosters economic growth by limiting the encroachment of a country's political system upon its markets. *Id.* at 3-4; *Preserving the American Common Market*, 7 S. Ct. Econ. Rev. at 235.

A. By Reinvesting Profits into Research and Development, American Pharmaceutical Companies Lead the World in the Creation of Life-Saving and Life-Enhancing Drugs

The American common market has created the most successful pharmaceutical industry in the world. Among the world's top 15 companies in the innovative drug industry in 1991, 8 were based in the United States. GAO, Report to the Chairman, Special Committee on Aging, U.S. Senate, *Prescription Drugs: Spending Controls in Four European Countries*, GAO/HEHS-94-30 (1994) (*Prescription Drugs*). United States-based pharmaceutical firms developed over 40 percent of the new major global drugs discovered between 1970 and 1992. *Id.* Success in this case is measured not only by the number of dollars in revenue, but by the number of lives saved and enhanced. American pharmaceutical companies generate more new and improved drugs than any other country. The reason can be traced to investment in R&D. Countries with higher drug prices tend to be associated with more pharmaceutical R&D and many new drugs. Conversely, in low-

price countries like Spain and Australia, R&D spending is low and very few new drugs are developed. *Prescription Drugs*, GAO/HEHS-94-30, at ch. 3:2.2. United States companies invest in the drawn-out development of new drugs because (1) they look forward to recovering their investment if the drug makes it through the gauntlet to be certified by the Food and Drug Administration (a process estimated to take 12 years with an average cost of $194 million (1990 dollars, net of various tax breaks) Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks, and Rewards*, OTA-H-522 at 1 (1993) (*Costs, Risks and Rewards*)); and (2) they enjoy national patent protection for the first few years the drug is on the market.

Pharmaceutical R&D is risky and expensive. Grabowski, Henry, *The Impact of the Clinton Health Care Reform Plan: Health Reform and Pharmaceutical Innovation*, 24 Seton Hall L. Rev. 1221, 1234-40 (1994) (*Pharmaceutical Innovation*); *see also* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 2-3 (July, 1998) (*Increased Competition*). Drug developers invest heavily in R&D because they expect to profit from it. *Increased Competition* at 2 ("Producers of innovator drugs invest heavily in research and development (R&D), hoping to recoup that investment in profits from future sales while a drug is under patent and they have a monopoly on its manufacture."); *see also Pharmaceutical Innovation*, 24 Seton Hall L. Rev. at 1258 ("A firm undertaking long-term risky R&D programs on new drugs must make an investment decision on the bases of expectations."). Higher drug prices strengthen the incentive for R&D. The GAO estimated that a 1% decline in drug prices leads to a 0.68% decline in R&D spending. This is consistent with previous economic analyses of the pharmaceutical industry, in which other measures of the incentive for R&D—for example, firms' profit rates and market shares—were positively related to R&D. GAO, *Prescription*

Drugs, GAO/HEHS-94-30, at ch. 3:3 (citing Comanor, William S., *The Political Economy of the Pharmaceutical Industry*, 24 Journal of Economic Literature 1178 (1986)); U.S. International Trade Commission, Report to the Committee on Finance, U.S. Senate, *Global Competitiveness of U.S. Advanced-Technology Manufacturing Industries: Pharmaceuticals*, US ITC Pub. 2437 (1991).

The dramatic increase in real revenues to new drugs throughout the 1980s sent signals to the industry that more investment would be rewarded handsomely. The industry responded by increasing its commitment to investment in R&D. *Costs, Risks and Rewards*, OTA-H-522 at 104; *Wrong Prescription*, 12 Fordham Intell. Prop. Media & Ent. L.J. at 906. A few "blockbuster" drugs have generated incredible profits for their patent owners. Stanton, Jerry, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 Conn. J. Int'l L. 149, 169 (2000) (*Lesson*) (citing Grabowski, Henry, *Health Reform and Pharmaceutical Innovation* 13-25 (1994)). But laws that would limit the amount that drug developers can make from future blockbuster drugs would drastically reduce the expected profits for drug developers, and therefore would drastically reduce investment in pharmaceutical R&D. *Id.*[7]

R&D innovation further depends on patent protection because competing drug manufacturers would undersell the developers before the developers recouped their investment in R&D and made a profit from it. "Without patents, many new drugs could be easily and quickly duplicated by other

[7] While other options for funding R&D exist, such as debt financing and equity financing, these options are not feasible given the extremely high cost—if not outright impossibility—of gathering impartial information to provide to investors. This is why most major pharmaceutical companies finance their R&D through retained earnings. *Prescription Drugs*, GAO/HEHS-94-30 at App. V:2.2 n.8.

manufacturers, preventing the innovator firm from obtaining enough reward to justify its investment." *Increased Competition* at 3. With patent protection, a drug developer looks to demand a price high enough to recoup the costs of R&D and make a profit. *Id.* Patents do not guarantee a profit for drug developers, but they make it a possibility by allowing drug developers to demand higher prices than they could without patent protection. *Wrong Prescription*, 12 Fordham Intell. Prop. Media & Ent. L.J. at 903-04.

R&D clearly emerges as the primary cause of American dominance in pharmaceutical innovation. Moreover, by advancing the state of scientific and medical knowledge, R&D benefits society above and beyond revenue received by direct sales of the resulting drugs. *Prescription Drugs*, GAO/HEHS-94-30 at Appendix V:1. The national commitment to maintaining America's standing as the leader in pharmaceutical development must not be undermined by this Court's approval of a states' efforts to reduce drug prices for their populations.[8]

B. Pharmaceutical Price Controls Have a Direct, Adverse Impact on Research, Development, and Innovation

Possibly the biggest threat to pharmaceutical companies who do business in Maine is the prospect of price controls if the "negotiations" on rebates do not favor the state in the amount the state deems appropriate. Me. Rev. Stat. tit. 22, §§ 2691, 2693(1). Price controls enacted by even one state can damage the American common market in pharmaceuticals. But price controls are unlikely to remain so contained. Protectionist politics invite retaliatory protectionism by other states, until

[8] Congress may be willing to risk some trade-offs between price reduction and R&D. *See, e.g.*, H.R. 5186 (Drug Importation Act of 2002) (permitting reimportation of drugs from Canada at possibly lower prices). The wisdom of such a choice is not before this Court, and, at any rate, does not implicate the Commerce Clause.

protectionists dominate in all states. *Economic Union*, 63 N.Y.U. L. Rev. at 77. Specific to this case, twenty-three states already have considered enacting "clones" of the Maine Rx Program legislation. Woellert, Lorraine, *The States Step into the Breach*, Bus. Week, Aug. 6, 2001, at 33. If this Court's decision invites these other states to follow Maine's example, lessons learned by other nations' imposition of price controls suggest that American patients will surely suffer.

Canada, the United Kingdom, France, Japan, and other countries have implemented pharmaceutical price controls for many years. *Lesson*, 16 Conn. J. Int'l L. at 160-64; *see also* Danzon, Patricia M., *Pharmaceutical Price Regulation* 15-29 (Ann Petty ed., 1997). The forms of their price regulations vary, but they all stifle competition and discourage innovation in the pharmaceutical industry. *Lesson*, 16 Conn. J. Int'l L. at 165-71; *Pharmaceutical Price Regulation* at 58-64. In many of these countries, purchasing power is lower than in the United States, and in most of these countries, the level of research and development of pharmaceuticals is not as extensive as in the United States. *Role of the State*, 56 Food Drug L.J. at 269 (citing Kolassa, Eugene M., *Elements of Pharmaceutical Pricing* 108-09 (Haworth Press 1997).

A study by Wharton economist Patricia Danzon used empirical evidence to thoroughly examine the effects of each of these countries' price regulations on incentives for pharmaceutical innovation, production efficiency, goals of controlling total drug expenditures, and quality of patient care. *Pharmaceutical Price Regulation* at 3-4. The evidence showed that no country with price controls has had innovative success in the pharmaceutical industry that matches that of the United States. *Id.* at 58-63. In fact, Danzon found "a rough negative correlation between the stringency of a country's price controls

and the innovative success of its domestic pharmaceutical industry." *Id.* at 63.

France, Germany, Sweden, and the United Kingdom have adopted price restraint mechanisms. Although they differ in their application, these countries' measures did lower prescription drug prices. However, these policies created a conflict between the interest in containing prescription drug costs and the economic burden subsequently borne by the domestic pharmaceutical industry, particularly on pharmaceutical R&D. This tension transcended the specifics of each country's pharmaceutical policies. *Prescription Drugs*, GAO/HEHS-94-30, at ch. 3.1. Based on its analysis of the four counties noted above, the GAO found that a reduction in prescription drug prices can be expected to reduce companies' spending on pharmaceutical R&D because firms will have less incentive to invest in R&D when they expect to receive lower prices for their products. *Id.*

Price controls in other countries allow them to "free-ride" on American manufacturers who invest in innovation. *Pharmaceutical Price Regulation* at 93. Controlled prices that cover only slightly more than the marginal cost of manufacturing a drug discourage pharmaceutical innovation by making R&D a less profitable investment. *Wrong Prescription*, 12 Fordham Intell. Prop. Media & Ent. L.J. at 913. Recognizing this cause and effect, the United States has pressured other countries to relax their regulations on drug prices. Harrison, Christopher Scott, Comment, *Protection of Pharmaceuticals As Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C. J. Int'l L. & Com. Reg. 457, 457-62 (2001) (discussing how the United States

pressured Canada to abandon its compulsory licensing law for patented pharmaceuticals).

From a public policy perspective, little can be gained from the imposition of price controls over new drugs and a great deal lost. Even if the government eliminated all profits from future drugs coming into the market, the prospective savings in terms of overall health care costs would be less than one percent of health care costs. *Wrong Prescription*, 12 Fordham Intell. Prop. Media & Ent. L.J. at 900. However, these actions would have precipitous effects on the incentives for research on innovative new medicines. Over the long term, patient welfare would be lower and total health care costs higher. *Pharmaceutical Innovation*, 24 Seton Hall L. Rev. at 1259.

Maine holds out the most feared consequence for pharmaceutical companies' failure to "negotiate" to the state's desired outcome: price controls. The certain adverse effect of price controls on America's premier pharmaceutical industry is a factor this Court should consider as it analyzes the impact of Maine Rx on the American common market.

CONCLUSION

Maine Rx would force pharmaceutical companies to provide drugs to Maine residents at lower prices than are available to the rest of the country. As a consequence, Americans not residing in Maine are likely to pay higher drug prices to make up the difference. Moreover, Maine's threatened price controls coerce cooperation in the Maine Rx statutory scheme. This is protectionist legislation that cannot be sanctioned under the dormant Commerce Clause.

The judgment of the First Circuit Court of Appeals should be reversed.

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Respectfully submitted,

DEBORAH J. LA FETRA
Counsel of Record
Pacific Legal Foundation
10360 Old Placerville Road,
Suite 100
Sacramento, California 95827
Telephone: (916) 362-2833
Facsimile: (916) 362-2932

Counsel for Amicus Curiae
Pacific Legal Foundation